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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/355,637 | 08/02/1999 | KLAUS-DIETER HAMMER | 051009/0122 | 6739 |

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FOLEY & LARDNER
3000 K STREET SUITE 500
PO BOX 25696
WASHINGTON, DC 200078696

EXAMINER

HON, SOW FUN

ART UNIT PAPER NUMBER

1772

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/355,637

Applicant(s)

HAMMER ET AL.

Examiner

Sow-Fun Hon

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 30 June 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment to advisory action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1-13, 15, 16 and 18-29.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: Attachment to advisory action

Advisory Action

1. The amendments to claims 1 and 24 have been entered since they are to correct typographical errors which do not affect the grounds of rejection in the Office action dated 12/31/03.
2. The request for reconsideration fails to place the application in condition for allowance for the reasons set forth below.
3. Applicant argues that Hammer fails to disclose edible shaped bodies instead of biodegradable sausage casings.

Applicant is respectfully reminded that the shaped bodies are inherently edible because the components of the composition are edible, as defined by Applicant's specification. The tubular film of Hammer is based on thermoplastic starch, an edible biopolymer (as defined by Applicant in original claim 2), and is produced by the following process. The biopolymer is mixed with at least one plasticizer, such as diglycerol or sorbitol (page 4, paragraph 2) which is edible (as defined by Applicant in original claim 4), at least one lubricant, such as lecitin or vegetable oil (page 6, paragraph 1) which is edible (as defined by Applicant in original claim 6), at least one crosslinker such as dialdehyde, dicarboxylic acid, di-isocyanate or diepoxide (page 5, paragraph 2) which is edible (as defined by Applicant in original claim 8).

Therefore the shaped tubular film of Hammer is inherently edible, as defined by Applicant.

4. Applicant argues that Hammer evaluates the removability of the casing off the sausage, and that in light of the comments made by Hammer on the biodegradability and disposal of the

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sausage casing, one skilled in the art would be led to conclude that Hammer relates to inedible sausage casings.

Applicant is respectfully directed to the response of the Office above, which interprets the term "edible" based on Applicant's specification, the original claims being part of Applicant's specification. Furthermore, Hammer teaches potato starch as an example of thermoplastic starch (page 7, last paragraph). Potato starch is commonly known as an edible starch.

Applicant is also respectfully apprised that Applicant has not specified that the term "edible" should be equated with the term "palatable". Instead, Applicant has equated the term "digestible" with the term "edible" when teaching that the claimed fiber added to strengthen the casing is not digestible, but promotes digestion, being dietary fiber (Applicant's specification, page 6, lines 10-20).

5. Applicant argues that it is commonly known to those skilled in the pertinent art that casings with an elongation at break (in the dry state) in the range of the casings of Hammer in terms of 80 % in the longitudinal direction and about 100 % in the cross direction, are no longer chewable, and hence cannot be regarded as "edible".

Applicant is respectfully requested to provide an affidavit demonstrating that the difference in elongation at break (in the dry state) does indeed provide the difference in "chewability". Applicant is respectfully reminded that chewing gum shows a large elongation at break (in the dry state), and is very "chewable".

6. Applicant argues that the casings of Hammer have a wall thickness on the average of 90 microns which render them non-edible.

Applicant is respectfully apprised that 90 microns is merely 0.09 millimeters, which is already very thin. The upper limit of 60 microns, or 0.06 millimeters, as claimed by Applicant, is on the same order of magnitude.

7. Applicant argues that from a reading of Applicant's specification as a whole, that the term "edible" is clearly intended to mean "edible by human beings", that those skilled in the art would readily recognize the difference between edible casings and inedible casings which are peeled away and discarded.

Applicant is respectfully apprised that, as demonstrated by the response of the Office above, the sausage casing of Hammer is indeed edible by human beings, based on Applicant's definition of the term "edible", wherein Applicant's specification defines the components of the casing of Hammer to be "edible", and Applicant's specification has equated the term "edible" with "digestible" when describing the fibers claimed as being non-digestible, but promoting digestion, being "dietary fiber".

8. Applicant argues that Anderson does not provide motivation to incorporate fibers in an edible article because while Andersen teaches that the fibers improve the toughness and form stability of the article; this is just the opposite of what is desired for an edible article. Applicant argues that an edible article must not be tough, but rather needs to be chewable.

Applicant is respectfully requested to further clarify this argument since Applicant has brought up a potential lack of enablement issue. Applicant claims fiber (original claims 10-12) in an edible shaped body. Furthermore, Applicant has equated the term "digestible" with the term "edible" when teaching that the fiber added to strengthen the casing is not digestible, but

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promotes digestion, being dietary fiber (Applicant's specification, page 6, lines 10-20). Does Applicant now mean that the claimed fiber renders the sausage casing "inedible"?

9. Applicant argues that neither Hammer nor Andersen teach or properly suggest a shaped body exhibiting either longitudinal elongation at break of 12-15% or a transverse elongation at break of 20-26%, and that the Office does not specifically address either of said claims in the prior Office action.

Applicant is respectfully directed to paragraph 4 of the prior Office action dated 12/31/03. In said Office action, the composition of the tubular film of Hammer is described and demonstrated to be the same as the presently claimed edible shaped body of Applicant. Thus the claimed 12-15 % longitudinal elongation at break of the tubular film (shaped body) (claim 28) and the claimed 20-26 % transverse elongation at break (claim 29) are within the realm of routine experimentation, for one of ordinary skill in the art.

Applicant is also respectfully directed to the response of the Office above regarding the "chewability" of the sausage casing, bearing in mind that chewing gum is very chewable, but also has a large elongation at break.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon

Sow-Fun Hon

10/12/04

Harold Pyon
HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

10/20/04